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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,587	08/19/2003	Samuel Bogoch	9425/468031	2933

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,587	BOGOCH ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15 and 24-27* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/19/03; 5/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignments A and B*.

DETAILED ACTION

Response to Amendment

Applicant's election without traverse of Group III, claims 13-15 and 24-27, in the amendment filed on 29 June 2006 is acknowledged. Claims 1-12, 16-23 and 28-31 have been canceled, and claims 24 and 26 have been amended as requested in said amendment. Following the amendment, claims 13-15 and 24-27 are pending in the instant application.

Hence, claims 13-15 and 24-27 are under examination in the instant office action.

Information Disclosure Statement

Signed and initialed copies of the IDS papers filed 19 August 2003 and 06 May 2004 are enclosed in this action.

Specification

The disclosure is objected to because of the following informalities: The priority information at p.1, line of the specification requires updating, since the '144 application has issued as a patent.

Appropriate correction is required.

Claim Objections

Claim 25 is objected to because of the following informalities: It contains a typo, i.e., "comprising at least one blood collection tube or pipette and peptide having the

amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2." Appropriate correction is required, e.g. "and the peptide..."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 09/854,568. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 of the '568 application is directed to an antimalignin antibody. The instant specification at p.1, lines 30-32 teaches that SEQ ID NOs: 1 and 2 are constituents of aglyco 10B and thus "provide *in vivo* production of the specific antibody to aglyco 10B, anti-aglyco 10B (antimalignin antibody)". Thus, the antibody of claim 6 of the '568 application would specifically recognize "a peptide having the amino acid sequence of SEQ ID NO: 2", (which encompasses aglyco protein 10B or malignin), as in the instant claim 13, or would specifically recognize aglyco protein 10B, as in the instant claim 14.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 4,298,590. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 12-14 of the '590 patent are directed to an antimalignin antibody with additional limitations, e.g., being attached to a signal emitter.

Additionally, the antibody of claims 12-14 of the '590 patent would specifically recognize a peptide having the amino acid sequence of SEQ ID NO: 2, as in the instant claim 13, or would specifically recognize aglyco protein 10B, as in the instant claim 14.

Claim 24 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 4,298,590 in view of U.S. Patent No. 4,041,146 to Giaever. Claims 12-14 of the '590 patent are directed to an antimalignin antibody with additional limitations, e.g., being attached to a signal emitter. The antibody of claims 12-14 of the '590 patent differs from claim 24 herein in that it is not included in a pipette in a kit. However, the portion of the '590 patent that supports the use of the malignin/antimalignin antibody describes the advantages of coating the inner and outer surfaces of a tube with malignin (entire document; e.g., col.25, lines 1-24). Furthermore, the '146 patent discloses methods for the immunological detection of biological molecules in human blood by coating the inner surface of a test tube with antibodies to a specific antigen and then adding a blood sample suspected of containing the antigen (col.3, lines 5-61; col.5, line 20), as in the instant claim 24.

Therefore, it would have been obvious to modify the antibodies of claims 12-14 of the '590 patent such that they are coated in a test tube or pipette and included in a kit for diagnostic or therapeutic use as taught by the Giaever patent. The skilled artisan would have been motivated to make these modifications to optimize the diagnostic

and/or therapeutic use of the antimalignin antibody, as taught by the supporting portions of the '590 patent and the teachings of the Giaver patent.

Claims 13 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-11, 20 and 21 of U.S. Patent No. 4,486,538. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 7-11, 20 and 21 of the '538 patent are directed to compositions comprising a mixture of monoclonal antimalignin antibodies, i.e., antimalignin antibody-fast and slow with additional inherent limitations, (e.g. said antibody is cytotoxic to cancer cells). Additionally, the antibodies of claims 7-11, 20 and 21 of the '538 patent would specifically recognize a peptide having the amino acid sequence of SEQ ID NO: 2, as in the instant claim 13, or would specifically recognize aglyco protein 10B, as in the instant claim 14.

Claim 24 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-11, 20 and 21 of U.S. Patent No. 4,486,538 in view of U.S. Patent No. 4,041,146 to Giaever. Claims 7-11, 20 and 21 of the '538 patent are directed to an antimalignin antibody with additional limitations, e.g., being attached to a signal emitter. The antibodies of claims 7-11, 20 and 21 of the '538 patent differs from claim 24 herein in that they are not included in a pipette in a kit. However, the portion of the '590 patent that supports the use of the malignin/antimalignin antibody describes the advantages of coating the inner and outer

surfaces of a tube with malignin (entire document; e.g., Example 7). Furthermore, the '146 patent discloses kits and methods for the immunological detection of biological molecules in human blood by coating the inner surface of a test tube with antibodies to a specific antigen and then adding a blood sample suspected of containing the antigen (col.3, lines 5-61; col.5, line 20), as in the instant claim 24.

Therefore, it would have been obvious to modify the antibody of claim 6 of the '568 application such that it is coated in a test tube or pipette and included in a kit for diagnostic or therapeutic use as taught by the Giaever patent. The skilled artisan would have been motivated to make these modifications to optimize the diagnostic and/or therapeutic use of the antimalignin antibody, as taught by the supporting portions of the '538 patent and the teachings of the Giaver patent.

Claim 15 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,242,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of the '578 patent is directed to an isolated peptide having the amino acid sequence of SEQ ID NO: 1 and claim 5 of the '578 patent is directed to an isolated peptide having the amino acid sequence of SEQ ID NO: 2, whereas the instant claim 15 is drawn to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof.

Claims 25 and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,242,578 in view of U.S. Patent No. 4,041,146 to Giaever. Claim 4 of the '578 patent is directed to an isolated peptide having the amino acid sequence of SEQ ID NO: 1 and claim 5 of the '578 patent is directed to an isolated peptide having the amino acid sequence of SEQ ID NO: 2. The peptides of claims 4 and 5 of the '578 patent differ from claims 25 and 26 herein in that they are not included in a pipette in a kit. However, the portion of the '578 patent that supports the use of SEQ ID NOs: 1 and 2 describes the advantages of including them as coated in a pipette contained in a kit (entire document, e.g., col.18, lines 18-35). Furthermore, the '146 patent discloses kits and methods for the immunological detection of biological molecules in human blood by coating the inner surface of a test tube with antibodies to a specific antigen and then adding a blood sample suspected of containing the antigen (col.3, lines 5-61; col.5, line 20), a which is analogous to using antigens to detect antibodies, as in the instant claims 25 and 26.

Therefore, it would have been obvious to modify the peptides of claims 4 and 5 of the '578 patent such that they are coated in test tubes or pipettes and included in a kit for diagnostic or therapeutic use as taught by the Giaever patent. The skilled artisan would have been motivated to make these modifications to optimize the diagnostic and/or therapeutic use of the malignin (a peptide comprising SEQ ID NO: 1 or SEQ ID

NO: 2), as taught by the supporting portions of the '578 patent and the teachings of the Giaver patent.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic compositions comprising the peptides of SEQ ID NOs: 1 or 2, does not reasonably provide enablement for therapeutic compositions comprising a peptide of SEQ ID NO: 1 or a peptide of SEQ ID NO: 2.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The claim is directed to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof.

The claimed molecules, i.e., "a peptide of SEQ ID NO: 1" and "a peptide of SEQ ID NO: 2", encompass peptides that comprise as little as two amino acids of the claimed sequence identifiers to as much the full length sequences with an additional infinite number of amino acids. Thus, the claim is overly broad in the recitation of "a peptide of SEQ ID NO: 1" or "a peptide of SEQ ID NO: 2" since insufficient guidance is provided as to which of the myriad of amino acid species encompassed by the claim will retain the increasing antimalignin antibody concentration.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The claims, and the predictability of which amino acids or nucleic acids can be substituted is extremely complex and outside the realm of routine experimentation, because accurate predictions of an amino acid or a nucleic acid molecule's structure from mere sequence data are limited. Since detailed information regarding the structural requirements of any peptide of SEQ ID NO: 1 or SEQ ID NO: 2 are lacking, it is unpredictable as to which variations, if any, meet the limitations of the claims.

As an example of the unpredictable effects of mutations on protein function, Mickle et al. teaches that cystic fibrosis is an autosomal recessive disorder caused by abnormal function of a chloride channel, referred to as the cystic fibrosis transmembrane conductance regulator (CFTR) (page 597). Several mutations can cause CF, including the G551D mutation. In this mutation a glycine replaces the aspartic acid at position 551, giving rise to the CF phenotype. In the most common CF mutation, de1ta-F508, a single phenylalanine is deleted at position 508, giving rise to

the CF phenotype, thus showing that even the substitution or deletion of a single amino acid in the entire 1480 amino acid CFTR protein sequence can have dramatic and unpredictable effects on the function of the protein.

Additionally, it is known in the art that even a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Furthermore, Yan et al. teaches that in certain cases, a change of two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another (Yan et al., Two-amino acid molecular switch in an epithelial morphogen that regulates binding to two distinct receptors. *Science* 290: 523-527, 2000). Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claim encompasses a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof, it would require undue experimentation for one of skill in the art to make and use the claimed products.

Claim 15 is rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claim is directed to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof.

As stated above, the claimed molecules, i.e., "a peptide of SEQ ID NO: 1" and "a peptide of SEQ ID NO: 2", encompass peptides that comprise as little as two amino acids of the claimed sequence identifiers to as much the full length sequences with an additional infinite number of amino acids. Therefore, because claim 15 is directed to a plurality of undisclosed amino acid molecules, this is a genus claim. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure,

or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural features of each genus of amino acid sequences encompassed by "a peptide of SEQ ID NO: 1" or "a peptide of SEQ ID NO: 2" such that the skilled artisan can make and use the claimed genera. Thus, the scope of the claims includes numerous structural variants, and each genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the amino class are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, any peptide of SEQ ID NO: 1 and/or any peptide of SEQ ID NO: 2 are insufficient to describe the genera. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera. Thus, Applicants are not in possession of the claimed genera.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,486,538 to Bogoch.

Claims 13 and 14 are directed to a purified monoclonal antibody which specifically recognizes a peptide having the amino acid sequence of SEQ ID NO: 2 or a purified monoclonal antibody which specifically recognizes aglyco protein 10B. Claim 15 is directed to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof. Claim 27 is directed to an isolated nucleic acid encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2.

The '538 patent teaches monoclonal anti-malignin antibodies that bind to malignin (aglyco protein 10B or a peptide having the amino acid sequence of SEQ ID NO: 2; e.g. Abstract), thus meeting the limitations of claims 13 and 14. The patent also teaches that aglycoprotein 10B (malignin) causes production of antimalignin antibody *in vivo* and suggests a therapeutic use for raising said production in cancer patients, since it states that survival of cancer patients was directly related to the concentration of antimalignin antibody *in vivo* (col.3, lines 1-21), thus meeting the limitations of claim 15. Further, the patent discloses isolating nucleic acids that encode malignin and anti-malignin (col.3, lines 39-48). It is noted that claim 27 encompasses an isolated nucleic acid encoding malignin (a peptide comprising the amino acid sequence SEQ ID NO: 1

or SEQ ID NO: 2), thus the '538 patent meets the limitations of claim 27. Since the reference discloses all the elements of the claims, claims 13-15 and 27 are anticipated by the '538 patent to Bogoch.

Claims 15 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,298,590 to Bogoch.

The claim is directed to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof.

The '590 patent teaches that malignin (aglycoprotein 10B) causes production of antimalignin antibody and teaches that the antibody is useful in as a therapeutic in treating cancer (col.1, lines 15-24; col.2, line 32 – col.3, line 32), thus meeting the limitations of claim 15. Since the reference discloses all the elements of the claim, claim 15 is anticipated by the '590 patent to Bogoch.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Weston et al. (J Mol Biol. 1986 Nov 20;192(2):177-208).

As stated above, the claimed molecules, i.e., "a peptide of SEQ ID NO: 1" and "a peptide of SEQ ID NO: 2", encompass peptides that comprise as little as two amino acids of the claimed sequence identifiers to as much the full length sequences with an additional infinite number of amino acids.

Accordingly, the Weston et al. document teaches peptides that comprise 3 adjacent amino acids of Applicants' SEQ ID NO: 1 (see sequence alignment A), thus meeting the limitation of "a peptide of SEQ ID NO: 1" in claim 15. It is noted that the intended recited by claim 15, i.e., "a therapeutic peptide for increasing antimalignin antibody concentration in a patient in need thereof" does not impart patentable weight on the claim. Hence, claim 15 is anticipated by Weston et al.

Claim 15 is also rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Cell. 1989 Apr 21;57(2):233-42).

The Liu et al. document teaches peptides that comprise 4 adjacent amino acids of Applicants' SEQ ID NO: 2 (see sequence alignment B), thus meeting the limitation of "a peptide of SEQ ID NO: 2" in claim 15. Hence, claim 15 is anticipated by Liu et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,486,538 to Bogoch in view of U.S. Patent No. 4,041,146 to Giaever.

Claims 13 and 14 are directed to a purified monoclonal antibody which specifically recognizes a peptide having the amino acid sequence of SEQ ID NO: 2 or a purified monoclonal antibody which specifically recognizes aglyco protein 10B. Claim 15 is directed to a therapeutic composition for increasing antimalignin antibody concentration in a patient in need thereof comprising a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B,

and combinations thereof. Claim 24 is directed to a kit for determining the concentration of aglycoprotein 10B antigenic epitopes present in blood of a patient comprising at least one blood collection tube or pipette and antimalignin antibody wherein said antibody is coated on the inner surface of said test tube or pipette. Claims 25 and 26 are directed to a kit for determining the concentration of anti-malignin antibody present in blood of a patient comprising at least one blood collection tube or pipette and peptide having the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein said antibody is coated on the inner surface of the test tube or pipette. Claim 27 is directed to an isolated nucleic acid encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2.

As stated above, the instant specification at p.1, lines 30-32 teaches that SEQ ID NOs: 1 and 2 are constituents of Aglyco 10B and thus "provide *in vivo* production of the specific antibody to Aglyco 10B, anti-Aglyco 10B (antimalignin antibody)".

The '538 patent teaches monoclonal anti-malignin antibodies that bind to malignin (aglyco protein 10B or a peptide having the amino acid sequence of SEQ ID NO: 2; e.g. Abstract), as in claims 13 and 14. The patent also teaches that aglycoprotein 10B (malignin) causes production of antimalignin antibody *in vivo* and suggests a therapeutic use for raising said production in cancer patients, since it states that survival of cancer patients was directly related to the concentration of antimalignin antibody *in vivo* (col.3, lines 1-21), as in claim 15. Further, the patent discloses isolating nucleic acids that encode malignin (a peptide comprising SEQ ID NO: 1 or SEQ ID NO: 2) and anti-malignin (col.3, lines 39-48), as in claim 27.

Additionally, the '538 patent teaches coating the inner surface of a plastic tube with malignin (i.e., a peptide having the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2; col.17, line 64 – col.18, line 3). The '538 patent does not teach kits. However, the '146 patent discloses kits and methods for the immunological detection of biological molecules in human blood by coating the inner surface of a test tube with antibodies to a specific antigen and then adding a blood sample suspected of containing the antigen (col.3, lines 5-61; col.5, line 20), as in claims 24-26.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to arrive at the claimed invention by combining the antibodies, peptides and coated tubes of the Bogoch patent with the kits, assay methods and antibody coated tubes of the Giaever patent. The skilled artisan would have been motivated to make these modifications to easily and efficiently detect aglycoprotein 10B antigenic epitopes or antimalignin antibody in the blood, since said antibody is increased in patients with active cancer, thus providing a means for early cancer detection as taught by the Bogoch patent (entire document). The person of ordinary skill in the art would have had a reasonable expectation of success because the both patents teach that the products, methods, and kit would work (entire document).

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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